



County of Erie

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COMMISSIONER OF HEALTH

TO: All E.M.S. Providers

FROM: John Adolf, Deputy Commissioner / E.M.S.
Erie County Division of Emergency Medical Services

DATE: April 19, 2013

SUBJECT: Voluntary Recall of FreeStyle Insulinx® Blood Glucose Meters

Abbott Initiates Voluntary Recall of FreeStyle Insulinx® Blood Glucose Meters in the United States

At rare, extremely high blood glucose levels (1024 mg/dL and above), the FreeStyle Insulinx Blood Glucose Meter may provide an inaccurate reading

FOR IMMEDIATE RELEASE - April 15, 2013 - Abbott today announced it is initiating a voluntary recall of FreeStyle Insulinx® Blood Glucose Meters in the United States.

The company has determined that at extremely high blood glucose levels of 1024 mg/dL and above, the FreeStyle Insulinx Meter will display and store in memory an incorrect test result that is 1024 mg/dL below the measured result. For example, at a blood glucose value of 1066 mg/dL, the meter will display and store a value of 42 mg/dL (1066 mg/dL - 1024 mg/dL = 42 mg/dL). No other Abbott blood glucose meters are impacted by this issue.

Blood glucose levels at 1024 mg/dL and above are very rare. However, if high blood glucose levels of 1024 mg/dL and above do occur, they are a serious health risk and require immediate medical attention. As the FreeStyle Insulinx Meter can display an inaccurate low result at a blood glucose level above 1024 mg/dL, there may be a delay in the identification and treatment of severe hyperglycemia, or incorrect treatment may be given. This could lead to serious injury or death.

Customers who are using the FreeStyle Insulinx Meter should immediately take one of the following actions to address this issue with their meter:

- Customers can access a software update to resolve the issue at www.freestyleinsulinx.com/swupdate¹. The software update will allow customers to maintain settings and historical data on their meter.
- Customers can contact Abbott Diabetes Care Customer Service at 1-866-723- 2697 to expedite return and replacement of their FreeStyle Insulinx meter at no charge. Replacements are available, and Abbott will send meters to customers immediately upon request.

Until customers are able to update the meter software or until a requested replacement meter arrives, the current FreeStyle Insulinx meter may be used; however, if patients experience symptoms that are not consistent with their readings, they should contact their healthcare professional and follow his or her treatment advice.

"Our first priority is to safeguard the health and safety of patients," said Heather Mason, Senior Vice President, Diabetes Care, Abbott. "We are committed to ensuring that our customers are able to continue to test their blood glucose with confidence, and we initiated this voluntary recall to ensure our products continue to meet the highest standards of quality and safety. We regret any inconvenience this action may cause."

The company is notifying all registered users, healthcare professionals, pharmacies and distributors where the FreeStyle Insulinx Meter is sold. Abbott estimates that there are approximately 50,000 active FreeStyle Insulinx Meter users in the United States. Upon identifying the issue, Abbott promptly developed and implemented an update to the meter.

Cc Commissioner Burstein
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